REMARKS

Claims 1-24 are pending. Claims 5, 7, 13, 14 and 17-24 are withdrawn from consideration. Claims 1-4, 6, 8-12, 15 and 16 are rejected.

Information Disclosure Statement

In accordance with the Examiner's request, applicant has included a copy of the PTOL-1449 as received at the USPTO on August 4, 2003, and requests it be initialed as part of the record.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 1-4, 6, 8-12, 15 and 16 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over EP 0 970 711 A2 (Ethicon Inc.).

Claim 1 defines a coating for an implantable medical device comprising a first region having a drug and a second region on the top of the first region having a polymer. The polymer has a glass transition temperature between 35°C and about 50°C and contains less than about 1 mass % of water. The glass transition temperature of the polymer in the range between 35°C to 50°C allows the morphology of the polymer to change so as to cause the release rate of the drug to change when a body temperature of the patient in which the device has been implanted rises to a temperature above the patient's normal body temperature. By selecting a polymer having a glass transition temperature between 35°C and about 50°C to form the coating, the current invention provides for the modification of the drug release rate from the coating. Therefore, a polymer having a glass transition temperature in the range defined in claim 1 is an important feature of the coating of claim 1.

Further, the rate of release of the drug through the polymer of the topcoat layer is related to the rate of diffusion of the drug through the matrix. The rate of diffusion is in turn related to the water adsorption rate. The current invention defines a polymeric coating in a dry state

containing specifically less than 1 mass% of water for the smooth release of the drug. Thus, the percentage of water content is an important element of the coating which is necessary for controlling the rate of drug release from coating.

Ethicon discloses polymer coated stents. Non-acrylic polymers such as vinyl halides, polystyrenes and polyoxymethylenes are disclosed for their use in these polymer coatings at [0023]. Multiple coatings are suggested at [0028], with a topcoat suggested at [0029] in order to delay release of the pharmaceutical agent.

There is no teaching in Ethicon for one of ordinary skill in the art to select a polymer with a particular glass transition temperature as defined in claim 1 to cause a coating including the polymer to change morphology to control the drug release rate from the coating. Further, there is no suggestion in Ethicon for one of ordinary skill in the art to select a polymer with less than 1 mass % of water for controlling the rate of drug release. Finally, there is no motivation in Ethicon for one of ordinary skill in the art to use polymers of certain glass transition temperatures or having certain percentage of water content for controlling the drug release rate from the coating. Therefore, Ethicon does not render the claim 1 obvious.

As the Examiner correctly notes, Ethicon does not describe a coating having a polymer of the selected glass transition temperature or percentage of water content as defined in claim 1. However, in stating that these are measurements for which the ordinary practitioner can either access through reference texts such as the Merck Index, the Examiner appears to read these features as inherent properties of the coatings. Applicant respectfully points out that the glass transition temperature is not an inherent property of the polymer. One of ordinary skill in the art would recognize that the glass transition temperature of a polymer depends on many factors. For example, **polymers having different molecular weights can have different glass transition temperature. Polymers having different molecular weight distribution can have different glass transition temperature. Polymers containing different ratios of monomers can have different glass transition temperature. The polymeric coatings having different chemical composition can also have different glass transition temperature.** Therefore, Applicant respectfully submits that the Examiner's assertion is unfounded.

Accordingly, claim 1 is patentably allowable over Ethicon. Claims 2, 3, 4, 6, and 8 depend from claim 1 and are patentably allowable over Ethicon for at least the same reason.

Claim 9 defines a coating for an implantable medical device comprising a polymer and a drug. The glass transition temperature of the polymer is the temperature that allows the morphology of the polymer to change the release rate of the drug when a body temperature of the patient in which the device has been implanted rises to a temperature above the patient's normal body temperature. Thus, a glass transition temperature of the polymer controls the rate of drug release. As seen from the discussion of claim 1, Ethicon does not teach the coating defined by claim 9. Therefore, claim 9 is patentably allowable over Ethicon. Claims 10, 11, 12 15, and 16 depend from claim 9 and are patentably allowable over Ethicon for at least the same reason. Withdrawal of the rejection and allowance of the claims is respectfully requested.

CONCLUSION

Removal of the rejection and allowance of the claims is respectfully requested. If the Examiner has any questions or concerns, the Examiner is invited to call the undersigned attorney of record.

Respectfully submitted,

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